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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,668	12/05/2003	Peter M. Bonutti	2500DV2CN2DV3CN2	3159

7590 05/08/2006

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EXAMINER

THALER, MICHAEL H

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/729,668	BONUTTI, PETER M.	
	Examiner	Art Unit	
	Michael Thaler	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 8-23, 25-37, 59-77 and 102-104 is/are pending in the application.
- 4a) Of the above claim(s) 7, 9, 12 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8, 10, 11, 13, 15-23, 25-37, 59-77 and 102-104 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claims 7, 9, 12 and 14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on August 18, 2004.

Claims 69-71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no antecedent basis for "the instruments" in claim 69 and 70.

Claims 59-62, 64-70, 72, 73 and 104 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sheldon (3,417,745). Sheldon discloses the steps of positioning a cannula 5 to access a joint (col. 3, lines 3-36 and col. 9, lines 46-70), introducing an expandable bladder 57 into the joint through the cannula, inflating the expandable bladder to spread apart adjacent surfaces and distend the joint to enlarge a space between the adjacent surfaces of the joint (The expansion of the expandable body 57 within the inter-vertebral space creates space for viewing as described in col. 9, lines 66-70.) and removing the expandable bladder from the joint. Alternatively, it would have been obvious that the creation of this space between the

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vertebrae spreads the adjacent tissue surfaces apart since the creation of space where there was none necessarily involve the movement of tissue surfaces.

Claims 63, 71 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheldon (3,417,745). As to claim 63 and 74 Sheldon fails to specifically indicate that the herniated disc described from col. 1, line 51 to col. 2, line 7 is operated on. However, it is old and well known in this art to remove an intervertebral disc when it is diagnosed as being herniated in order to obtain the advantage of relieving pain. It would have been obvious to remove the herniated disc during the Sheldon procedure so that this procedure too would have this advantage. As to claim 71, Sheldon fails to disclose applying a vacuum to deflate the bladder 57. However, it is old and well known in this art to deflate a balloon by applying a vacuum to the balloon in order to obtain the advantage of quickly deflating it. It would have been obvious to use a vacuum to deflate the Sheldon bladder 57 so that it too would have this advantage. The above well known in the art statements are taken to be admitted prior art because applicant failed to traverse the examiner's assertions (M.P.E.P. 2144.03).

Claims 75-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheldon (3,417,745) in view of McDaniel

(4,501,266). Sheldon fails to disclose using the device in a knee. However, Sheldon does teach that the device may be used in areas of the body other than the spine (col. 2, lines 8-9). Further, McDaniel teaches that the knee is an area of the body that requires surgical intervention and distraction. It would have been obvious to use the Sheldon device in the knee for this reason. Bladder 57 of Sheldon is wedge-shaped as seen in figure 4.

Claims 1-5, 8, 10, 11, 13, 15-23, 25-37, 59-77 and 102-104 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,017,305. Although the conflicting claims are not identical, they are not patentably distinct from each other because the minor differences between the claims involve merely obvious differences.

Claims 1-5, 8, 10, 11, 13, 15-23, 25-37, 102 and 103 are otherwise allowable.

Applicant's arguments filed March 9, 2006 have been fully considered but they are not persuasive. Applicant admits, on page 13, lines 1-3 of the reply, that the inflatable member of Sheldon displaces soft tissue in the vicinity of the lens to improve viewing the spinal region. Claim 59 does not require the adjacent surfaces that are spread apart to be rigid or to be

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the vertebrae themselves (lines 5-6 of the claim) and therefore this portion of the claim is met by Sheldon. Applicant alleges, on page 13 of the reply, that Sheldon teaches away from use with a cannula which would not be used with the device having a piercing sharply pointed tip. This allegation is unfounded since member 5 of Sheldon is itself a cannula. Further, the cannula 5 has an open distal end as indicated in col. 3, lines 8-10 which states "Therefore, the tip 5b consists only of the bottom wall 5c and side walls 5d and has no closing wall above the bottom wall". Further, the text in col. 9, lines 59-70 indicates that the spinescope with an inflatable member is inserted into and through the needle and then into the inter-vertebral space.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated

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from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (571)272-4704. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

mht
5/3/06



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731